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KAISER FOUNDATION HEALTH PLANS, INC.

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA – WESTERN DIVISION

KAISER FOUNDATION HEALTH PLAN, INC.,

Plaintiff,

v.

ABBOTT LABORATORIES,

Defendant,

CASE NO. CV- 02-02443-JFW (FMOx)

KAISER'S NOTICE OF MOTION AND MOTION FOR PARTIAL SUMMARY JUDGMENT

Date: October 5, 2009
Time: 1:30 p.m.
Place: Courtroom 16

Pretrial Conference Date: January 8, 2010
Trial Date: January 26, 2010

TO ALL PARTIES AND TO THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that on October 5, 2009, at 1:30 p.m., or as soon thereafter as the matter may be heard, in Courtroom F of the Honorable John F. Walter, of the above-entitled Court, located at 312. N. Spring Street, Los Angeles, California 90012, Plaintiff Kaiser Foundation Health Plan, Inc. ("Kaiser") will and hereby does move for an Order granting judgment as a matter of law, pursuant to Federal Rule of Civil Procedure 56(c); and finding that, for purposes of Kaiser's Sherman Act Section 2 claim, Defendant Abbott Laboratories ("Abbott") possessed monopoly power.

This Motion is based upon this Notice of Motion and Motion, the Memorandum of Point and Authorities, the Statement of Undisputed Material Facts and any exhibits thereto, and the Declaration of Hardy Vieux and any exhibits thereto filed concurrently herewith, any reply papers that are filed in further support of Kaiser's motion, all matters of which judicial notice may be taken, the Court's files, and such other oral and written evidence and argument as may be presented at or before the hearing or otherwise properly come before the Court.

Certification of Compliance with Central District Local Rule 7-3

This Motion is made following the conference of counsel, pursuant to Local Rule 7-3, which took place prior to the June 1, 2009 status conference. Counsel also have had discussions regarding the bases for this Motion during July and August of 2009.

Dated: August 25, 2009

Respectfully submitted,

BLANK ROME LLP

By: /s/ Hardy Vieux
Attorneys for Plaintiff, Kaiser Foundation Health Plan, Inc.

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MEMORANDUM OF POINTS AND AUTHORITIES

Plaintiff Kaiser Foundation Health Plan, Inc., on behalf of itself, its subsidiaries, and Kaiser Foundation Hospitals (collectively, "Kaiser") and pursuant to Federal Rule of Civil Procedure 56 and Local Rule 7-5, respectfully submits this Memorandum of Points and Authorities in support of its Motion for Partial Summary Judgment as to Abbott's Monopoly Power ("Motion").

PRELIMINARY STATEMENT

This case involves the drug terazosin hydrochloride ("terazosin"), a drug used to treat enlarged prostate and hypertension. Defendant Abbott Laboratories ("Abbott") at all times material hereto manufactured brand-name terazosin, commonly known as Hytrin. Abbott began selling Hytrin in 1987 and, until August 1999, Abbott was the only supplier of terazosin. (See Statement of Uncontroverted Facts at ¶ 1.)[1] During that time, Abbott maintained the price of Hytrin at a supracompetitive level, meaning that the price of Hytrin was above the price that would be charged in a competitive market. In this case, Kaiser maintains that, in violation of Section 2 of the Sherman Antitrust Act ("Sherman Act"), Abbott deceived the Patent and Trademark Office ("PTO") by knowingly and willfully misrepresenting facts in connection with an application for a patent covering terazosin and, thus, obtained the patent by fraud. The design and effect of Abbott's procuring this patent by fraud was to delay the entry of generic terazosin into the market, which caused Kaiser to pay a supracompetitive price for terazosin for an extended period of time.

Section 2 of the Sherman Act makes it unlawful to monopolize, attempt to monopolize, or conspire to monopolize interstate or international commerce. An antitrust claim under Section 2 requires proof of two elements: (1) the possession of monopoly power; and (2) the willful acquisition or maintenance of that power. Kaiser

[1] Kaiser has filed the Statement of Uncontroverted Facts and Conclusions of Law concurrently with this Motion. Included within that document are Additional Uncontroverted Facts.

seeks summary judgment only with respect to the first element of its Section 2 monopolization claim: that is, Abbott possessed monopoly power prior to generic terazosin coming to market in August 1999. Whether Abbott unlawfully acquired or maintained this monopoly power will be decided by the jury at trial with additional evidence not relevant to the instant Motion.

Monopoly power, the first element of a Sherman Act Section 2 claim, may be established by either direct evidence or circumstantial evidence. Courts have long recognized that the best evidence of monopoly power is direct evidence of the defendant's actual control over prices or its actual exclusion of competition. Direct evidence of supracompetitive prices, restricted output, or other actual anticompetitive effects establishes monopoly power as a matter of law. Conversely, proving monopoly power with circumstantial evidence often requires a more elaborate economic analysis, including a definition of the relevant market and the calculation of the defendant's market share within that market.

Here, undisputed direct evidence establishes that Abbott maintained prices of Hytrin at a supracompetitive level and excluded competition prior to generic terazosin coming to market in August 1999, rendering it superfluous to define a theoretical relevant market and to calculate Abbott's share in that market. The direct evidence includes:

1. Abbott's internal admission that it controlled the market for terazosin when, in 1997, it internally projected that if and when generic terazosin entered the market, Abbott would lose 40% of its Hytrin sales within two months and 80% of its Hytrin sales within a year, amounting to over $22 million per month in lost profits;
2. Abbott's acknowledgement that its monopoly power would be destroyed and its monopoly profits threatened were generic terazosin to come to

market, when it agreed to pay Geneva Pharmaceuticals $4.5 million per month not to come to market with generic terazosin; and

3. The dramatic impact of the entry of generic terazosin and competition when, (a) just after generic terazosin came to market in August of 1999, Abbott offered to sell Hytrin to Kaiser for just $0.10 per tablet rather than the $0.70 per tablet Abbott had been charging Kaiser—an 85% reduction in price; and (b) one year after generic terazosin entered the market, Abbott's Hytrin sales plummeted over 75%—just as Abbott had predicted would happen;

This undisputed direct evidence of Abbott's ability to charge supracompetitive prices and to exclude competition as well as the dramatic effect on Abbott's prices, sales volume, and profits immediately following the collapse of its market position establishes that Abbott possessed monopoly power prior to generic terazosin coming to market in August of 1999.

BACKGROUND

I. REGULATORY BACKGROUND

Under the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355 ("Hatch-Waxman Act"), a drug manufacturer seeking the Food and Drug Administration's ("FDA") approval to sell a generic version of a patented, brand-name drug may file an Abbreviated New Drug Application ("ANDA") in order to establish that its generic version is the "bioequivalent" of an already FDA-approved brand-name drug. (See Additional Undisputed Facts [hereinafter "AUF"] ¶ 1.) An ANDA applicant who, in connection with its application, certifies that the patent of the brand-name drug is either invalid or will not be infringed by the generic drug must notify the holder of the brand-name patent of its ANDA. (AUF ¶ 2.) This certification entitles the ANDA applicant to a 180-day period of exclusive distribution of the generic drug upon its approval by the FDA. (AUF ¶ 3.) FDA approval is made

effective immediately unless the holder of the brand-name patent files an infringement suit under the Hatch-Waxman Act within forty-five days of the notification by the ANDA applicant. (AUF ¶ 4.) By filing an infringement suit within the forty-five-day period, the holder of the brand-name patent generally delays what would otherwise have been automatic FDA approval for a period of thirty months commonly referred to as the "automatic stay." (AUF ¶ 4.)

If, however, the holder of the brand-name patent fails to file an infringement suit under the Hatch-Waxman Act within the forty-five-day period, it forfeits the automatic stay of the FDA approval process and also must wait to bring an infringement suit until the generic drug is sold commercially. 552 F.3d at 1037 (citing 35 U.S.C. § 271(e)(1)). Additionally, once the generic drug is approved by the FDA, the generic drug may be sold notwithstanding the pendency of any subsequently-filed infringement suit. Id.

II. FACTUAL BACKGROUND

A. The Parties

Kaiser is a health care provider that purchases large quantities of prescription drugs from manufacturers such as Abbott. (AUF ¶ 5.) Abbott develops and manufactures brand-name drugs, including Hytrin. (AUF ¶ 6.) Non-party Geneva Pharmaceuticals ("Geneva") manufactures generic drugs, including generic terazosin. (AUF ¶ 7.)

B. Abbott's Terazosin Patents and Fraud on the Patent Office in Connection with Its Application for the '207 Patent

After first patenting terazosin in 1977, Abbott continued to patent other forms of terazosin. (AUF ¶ 8.)When these add-on patents are legitimately obtained, they may extend the period of exclusivity enjoyed by a drug manufacturer. Relevant for purposes of this motion, Abbott filed Patent 5,504,207 (" '207 patent") in October of 1994, seeking to patent a different crystalline polymorph of terazosin just as its other,

active patents were set to expire. (AUF ¶ 9.) Kaiser maintains that without Abbott's having procured the '207 patent, generic terazosin would have come to market at the latest in April 1998.

In this case, Kaiser further maintains that Abbott knowingly and willfully omitted information from its PTO filings that, if included, would have prevented the '207 patent from being issued. These omissions were in connection with its submissions of "prior art" and "prior sales"—areas that may jeopardize the issuance of a patent. With respect to "prior art," Abbott furnished an abstract of an earlier Japanese patent application, but failed to furnish an English translation of the Japanese patent application that disclosed the same form of terazosin Abbott sought to be covered by the '207 patent. (AUF ¶ 10.) With respect to "prior sales," a patent will not issue under certain circumstances if the thing sought to be patented has been sold before. Here, Abbott disclosed prior sales, justifying its patent application notwithstanding these sales on its nuanced legal theory that the "on-sale bar" does not apply when the purchasers in prior sales did not know that the version of the terazosin they had purchased was the specific crystalline polymorph Abbott sought to cover in the '207 patent application. (AUF ¶ 11.) In its submission, Abbott purposefully withheld adverse, Federal Circuit case law on this issue,[2] having selectively cut and pasted into its submission an argument section pertaining to the applicability of the "on sale" bar from a brief Abbott had filed in a prior infringement suit, carefully excising from this identical argument the citation and attempted distinguishing of the adverse case. The '207 patent was issued on April 2, 1996, (AUF ¶ 12.)which would not have occurred but for Abbott's knowing and willful misrepresentation and withholding of material facts and legal authority from the PTO.

[2] The case Abbott omitted from its submissions was J.A. LaPorte, Inc. v. Norfolk Dredging Co., 787 F.2d 1577 (Fed. Cir. 1986).

C. Abbott Uses the Fraudulently-Obtained '207 Patent to Suppress Generic Competition

Between 1993 and 1998, Geneva and several other generic manufacturers filed a series of ANDAs seeking FDA approval of generic versions of terazosin. (AUF ¶ 13.) Geneva, which filed ANDAs for both a tablet and capsule form of generic terazosin, and the other generic drug manufacturers certified that Abbott's patents, including the '207 patent, were either invalid or were not infringed by the generic versions of the drug and provided notice to Abbott. 552 F.3d at 1039-40; (AUF ¶ 14.)Abbott had forty-five days from the notice of each certification to file infringement suits under the Hatch-Waxman Act. Id. at 1037 (citing 21 U.S.C. § 355 (j)(5)(B)(iii)); (AUF ¶ 15.)

In response, Abbott brought patent infringement suits against the generic manufacturers, including an infringement suit against Geneva in response to the ANDA it had filed for a tablet form of generic terazosin ("Tablet ANDA"), in which Abbott contended that the generic version at issue in the Tablet ANDA would violate its '207 patent. (AUF ¶ 16.) However, Abbott neglected to file an infringement suit in response to the ANDA Geneva had filed for a capsule form of generic terazosin ("Capsule ANDA"), which would likewise have infringed the '207 Patent. (AUF ¶ 18.) As a result of Abbott's failure to file a timely infringement suit under the Hatch-Waxman Act with respect to the Capsule ANDA, Abbott forfeited the automatic stay of FDA approval, and the FDA approved Geneva's capsule version of generic terazosin on March 30, 1998. (AUF ¶ 18.)Upon the FDA's approval of its ANDA, Geneva was free to come to market with its generic terazosin capsule.

However, on April 1, 1998—just two days after Geneva obtained FDA approval of its Capsule ANDA—Abbott reached an agreement with Geneva to prevent generic terazosin from entering the market ("Geneva Agreement"). (AUF ¶ 19.)In exchange for Abbott's monthly payment of $4.5 million, Geneva agreed not to market its

generic terazosin until the earliest of (1) the sale of generic terazosin by another manufacturer; (2) entry of a final, unappealable judgment concerning the validity of the '207 patent; or (3) February 17, 2000 (the date one of Abbott's other patents expired).[3] (AUF ¶ 20.) Kaiser maintains that, without the existence of the '207 patent and the corresponding risk to Geneva of liability in a patent infringement suit based on the '207 patent, Geneva would not have agreed to refrain from coming to market with generic terazosin in April 1998. (AUF ¶ 21.)

D. The Federal Circuit Rules that Abbott's '207 Patent is Invalid under the "On-Sale Bar," Resulting in the Termination of the Geneva Agreement and Geneva's Entry into the Market

During this time, Abbott's infringement suit against Geneva in response to Geneva's ANDA for a *tablet* form of terazosin continued[4]. (AUF ¶ 21.) In that suit, Geneva contended that the '207 patent was invalid under the "on-sale bar" of 35 U.S.C. § 102(b) because the form of terazosin covered by the '207 patent had been sold in excess of three times more than a year before Abbott filed the '207 patent. (AUF ¶ 22.) The court rejected Abbott's argument that the "on-sale bar" did not apply because the purchasers did not know that the version of the terazosin they had purchased was the specific crystalline polymorph covered by the '207 patent. (AUF ¶ 24.) The district court, and ultimately the Federal Circuit, agreed with Geneva that "knowing" use was not required (citing the very case that Abbott had chosen to omit from its patent submission) and declared Abbott's '207 patent invalid. (AUF ¶ 25.) After the Federal Circuit affirmed the district court's ruling on July 1, 1999, Abbott

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[3] Abbott reached a similar, multi-million-dollar-per-month agreement with Zenith-Goldline ("Zenith"), another manufacturer seeking to market generic terazosin, pursuant to which Zenith could market generic terazosin on February 17, 2000 or the date another generic manufacturer began to sell generic terazosin, whichever occurred first. (AUF ¶ 23.).

[4] As previously stated, Abbott did not timely file a patent infringement suit under the Hatch-Waxman Act in response to Geneva's Capsule ANDA, but did file an infringement action concerning Geneva's Tablet ANDA.

terminated the agreements it had with Geneva and Zenith for the suppression of generic terazosin. (AUF ¶ 25.) No longer constrained by the risk of infringing the '207 patent, Geneva entered the market and began selling generic terazosin in capsule form the very next month, (AUF ¶ 26.) resulting in the immediate and dramatic decline in the price for which Kaiser was able to purchase terazosin.

Although the Federal Circuit's ruling eventually invalidated the '207 patent, the '207 Patent would never have been issued had Abbott not knowingly and willfully misrepresented material facts to the PTO. Without the '207 patent, Abbott would not have been able to delay the approval of the ANDAs filed by Geneva and other generic manufacturers because (1) it would have had no basis for its infringement suits under the Hatch-Waxman Act (including the suit that eventually led to the invalidation of the '207 Patent); and (2) it would not have been able to secure Geneva's agreement to refrain from coming to market with generic terazosin in exchange for a $4.5-million-per-month payment. In short, had Abbott not procured the '207 patent by fraud, generic terazosin would have come to market much sooner than August 1999, and Kaiser would have been able to purchase terazosin at a competitive price earlier.

E. Abbott's Supracompetitive Pricing of Terazosin before Generic Terazosin Came to Market

Before generic terazosin came to market in August 1999, Abbott was the only seller of a pharmaceutical product containing the active ingredient terazosin. (AUF ¶ 27.) Hytrin was extremely lucrative for Abbott, generating $540 million in annual sales and representing more than 20% of its domestic pharmaceutical sales. (AUF ¶ 28.) Abbott's internal models and memoranda show that it was fully aware that the entry of generic terazosin into the market would have a catastrophic effect on sales volume and revenue. (AUF ¶ 29.) These models and memoranda predicted that within just two months of generic terazosin's coming to market, Abbott's Hytrin sales would plummet 40% and after a year would fall over 80%. (AUF ¶ 30.) This

evidence (from Abbott's own files) is nothing short of an admission by Abbott that, once generic terazosin came to market and hence competition existed, its sales volume and profits would be dramatically and negatively affected by customers switching to its competitor's lower-priced generic terazosin. Abbott clearly knew, and understood, that its status as the sole supplier of terazosin allowed it to charge higher prices and generate exceptionally high profits as long as there was no generic competition.

Before the Federal Circuit ruled that the '207 patent was invalid, Abbott had been able to sell Hytrin to Kaiser in large volumes for approximately $0.70 per tablet.[5] (AUF ¶ 31.) In August 1999, after the Federal Circuit declared the '207 patent invalid and Geneva entered the market, Abbott could no longer maintain its supracompetitive price and offered to sell Hytrin to Kaiser for just $0.10 per tablet—an 86% reduction in price. (AUF ¶ 32.) Kaiser refused Abbott's offer and began to purchase generic terazosin from Geneva. (AUF ¶ 33.) The $0.70-per-tablet price Abbott charged Kaiser prior to Geneva's entering the market was a supracompetitive price, for Abbott determined that the competitive price for Hytrin was only $0.10 per tablet once competition actually existed. (AUF ¶ 34.)

Abbott's projections that the entry of generic terazosin into the market would drastically reduce its sales volume and revenue proved remarkably accurate. In July 1999, the month before Geneva entered the market with generic terazosin, Abbott sold nearly 35 million units of Hytrin for total revenue of approximately $43 million. (AUF ¶ 35.) By October 1999, two months after Geneva came to market with generic terazosin, Hytrin sales had fallen to just over 20 million units for a total revenue of approximately $25 million—a 42% drop. (AUF ¶ 36.) By August 2000, one year after Geneva began to sell generic terazosin, Hytrin sales had fallen to 11.4 million units for a total revenue of under $10.4 million—a 76% drop. (AUF ¶ 37.) It is thus

[5] Notwithstanding the fact that Kaiser had purchased Hytrin in large volumes, it was still forced to pay the supracompetitive price of $0.70 per tablet until generic terazosin entered the market. (AUF ¶ 39.)

undisputed that, with the advent of competition from generic terazosin, Abbott's sales volume and revenues for Hytrin plummeted from 35 million units and $45 million in July 1999 to just 11 million units and $10 million in August 2000. (AUF ¶ 38.)

III. PROCEDURAL HISTORY

A. Lower Court Proceedings

On March 22, 2002, Kaiser sued Abbott, among others, in this Court, asserting claims under Sections 1 and 2 of the Sherman Act and analogous provisions of California law. (AUF ¶ 40.) Kaiser's Section 1 claim alleged that the Geneva Agreement was an illegal restraint of trade. Kaiser's Section 2 claim alleged that Abbott illegally sought to enhance its monopoly power and delay the entry of generic drug competition by filing sham lawsuits and also by fraudulently obtaining the '207 patent, otherwise known as Walker Process fraud[6]. (AUF ¶ 41.)

In 2003, Kaiser's suit was transferred to a multi-district panel of the United States District Court for the Southern District of Florida ("MDL Court") and consolidated, for purposes of pretrial proceedings, with similar suits involving terazosin brought by other plaintiffs ("MDL"). (AUF ¶ 42.)

On August 31, 2004, the MDL Court granted summary judgment in favor of Abbott on Kaiser's Sherman Act Section 2 claim, holding that the Noerr-Pennington doctrine applied and immunized Abbott from antitrust liability based on (1) its multiple infringement suits against generic manufacturers of terazosin; and (2) Abbott's procurement of the '207 patent through fraud on the PTO. (AUF ¶ 43.) Accordingly, the MDL Court denied as moot Kaiser's motion for summary judgment with respect to Abbott's monopoly power. (AUF ¶ 44.) Nevertheless, the MDL Court later observed that "the Court [wa]s persuaded that Abbot[t] ha[d] power in the relevant market, which is the market for Hytrin and its generic bioequivalent forms of

[6] See Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 177 (1965), discussed I Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1068 (Fed. Cir. 1998), cert. denied, 525 U.S. 876 (1998).

terazosin hydrochloride," noting the fact that Abbott would pay a generic manufacturer an exclusion payment "indicate[s] that the pioneer [Abbott] exercises substantial power in the market." (AUF ¶ 45.)

In February 2005, the MDL Court transferred this action back to this Court for trial on the issues of causation and damages for Kaiser's Sherman Act Section 1 claim.[7] (AUF ¶ 46.) After a trial in March and April of 2006, the jury found in favor of Abbott on both issues. (AUF ¶ 48.)

B. Appeal to the Ninth Circuit and Remand of Kaiser's Sherman Act Section 2 Claim to this Court

Following the jury verdict, Kaiser appealed the MDL Court's grant of summary judgment on its Sherman Act Section 2 claim as well as this Court's judgment in favor of Abbott on Kaiser's Sherman Act Section 1 claim to the United States Court of Appeals for the Ninth Circuit. (AUF ¶ 49.)

The Court of Appeals affirmed this Court's judgment on Kaiser's Sherman Act Section 1 claim and the MDL Court's summary judgment on Kaiser's "sham litigation" claim, but reversed as to MDL Court's summary judgment on Kaiser's Walker Process fraud claim. (AUF ¶ 50.) The Court of Appeals held that there was sufficient evidence for a jury to find that Abbott's conduct before the PTO with respect to the '207 patent was fraudulent and remanded the matter to this Court for trial. (AUF ¶ 51.)

ARGUMENT

"Section 2 of the Sherman Act prohibits monopolies, attempts to form monopolies, as well as combinations and conspiracies to do so." Image Technical Services, Inc. v. Eastman Kodak Co., 125 F.3d 1195, 1202 (9th Cir. 1997) (citing 15

[7] The MDL Court already had ruled that the Geneva Agreement was a *per se* violation under Section 1 of the Sherman Act and had entered partial summary judgment on liability in favor of Kaiser on its Section 1 claim. (AUF ¶ 47.) Therefore, only the issues of causation and damages were left to be tried.

U.S.C. § 2); see also Kaiser, 552 F.3d at 1043; Broadcom Corp. v. Qualcomm Inc., 501 F.3d 297, 306 (3d Cir. 2007). It is "the provision of the antitrust laws designed to curb the excesses of monopolists and near-monopolists." Broadcom, 510 F.3d at 306 (citing LePage's, Inc. v. 3M, 324 F.3d 141, 169 (3d Cir. 2003) (en banc)). A Sherman Act Section 2 claim has two elements: (1) that the defendant possessed monopoly power; and (2) that the defendant willfully acquired or maintained that power. United States v. Grinnell Corp., 384 U.S. 563, 570-71 (1966).

In the instant Motion, Kaiser seeks summary judgment as to the first element only: that is, Abbott possessed monopoly power prior to generic terazosin entering the market in August 1999.

I. DIRECT EVIDENCE OF ABBOTT'S SUPRACOMPETITIVE PRICING AND SUPPRESSION OF THE ENTRY OF GENERIC TERAZOSIN ESTABLISHES ABBOTT'S MONOPOLY POWER AS A MATTER OF LAW

The first element of a Section 2 claim, monopoly power, "commonly referred to as market power," is "the power to control prices or exclude competition." Image Technical, 125 F.3d at 1202; see also NCAA v. Bd. of Regents, 468 U.S. 85, 109 n.38 (1984) (monopoly power is "the ability to raise prices above those that would be charged in a competitive market"); Jefferson Parish Hosp. Dist. No. 2 v. Hyde, 466 U.S. 2, 27 n.46 (1984) (monopoly power "exists whenever prices can be raised above levels that would be charged in a competitive market").

Monopoly power can be proven by either direct or circumstantial evidence. Image Technical, 125 F.3d at 1202 (citing Rebel Oil Co. v. Atlantic Richfield Co., 51 F.3d 1421, 1434 (9th Cir. 1995)); see also In re Abbott Labs. Norvir Anti-trust Litig., 552 F. Supp. 2d 1080, 1085-86 (N.D. Cal. 2008), rev'd on other grounds, 571 F.3d 930 (9th Cir. 2009) (discussing direct evidence of the defendant's price increase, the defendant's own internal predictions of the effect of the drug's price, and the actual effect of the price increase). Although antitrust plaintiffs often try to prove monopoly

power through indirect or circumstantial evidence, courts have long recognized that the best evidence of monopoly power is direct evidence of the defendant's actual control over prices or its actual exclusion of competition. See Am. Tobacco Co. v. United States, 328 U.S. 781, 810-11 (1946); Conwood Co. L.P. v. U.S. Tobacco Co., 290 F.3d 768, 783 n.2 (6th Cir. 2002); Byars v. Bluff City News Co., 609 F.2d 843, 850 (6th Cir. 1979). (See Statement of Conclusion of Law at ¶ 1.)

Furthermore, although courts often discuss the direct-evidence method of proving monopoly power in the context of "supracompetitive prices" or "restricted output," "[t]he defining characteristic of direct evidence is that it demonstrates actual injury to competition." In re Abbott Labs. Norvir Anti-trust Litig., 562 F. Supp. 2d at 1085 (rejecting defendant Abbott Laboratories' argument that direct evidence was limited to proof of "restricted output and consequent supracompetitive prices"). In other words, supracompetitive prices and restricted output are "sufficient" proof, but they are not "necessary" to establish monopoly power with direct evidence. Id.

Proving monopoly power through indirect or circumstantial evidence, on the other hand, requires a complex, fact-intensive analysis, for which:

> a plaintiff must: "(1) define the relevant market, (2) show that the defendant owns a dominant share of that market, and (3) show that there are significant barriers to entry and show that existing competitors lack the capacity to increase their output in the short run."

Image Technical, 125 F.3d at 1202-1203 (quoting Rebel Oil, 51 F.3d at 1434). This complex, fact-intensive analysis is simply not required when a party establishes monopoly power with direct evidence, as Kaiser does here.

Indeed, the Supreme Court emphasized in FTC v. Indiana Fed'n of Dentists, that direct evidence of control over prices or exclusion of competition, among other types of direct evidence of adverse effects on competition, makes the usual analysis of market definition and market shares (required where a plaintiff relies on circumstantial evidence) unnecessary:

> Since the purpose of the inquiries into market definition and market power is to determine whether an arrangement has the potential for genuine adverse effects on competition, proof of actual detrimental effects, such as reduction of output, can obviate the need for an inquiry into market power, which is but a surrogate for detrimental effects.

476 U.S. 447, 460-61 (1986) (citations omitted). Similarly, numerous circuit courts have held that courts need not engage in the market-definition/market-shares analysis if better, more direct evidence is available. See, e.g., Broadcom, 501 F.3d at 307 n.3 ("Because market share and barriers to entry are merely surrogates for determining the existence of monopoly power, direct proof of monopoly power does not require a definition of the relevant market."); Todd v. Exxon Corp., 275 F.3d 191, 206 (2d Cir. 2001) (quoting K.M.B. Whse. Distribs. v. Walker Mfg. Co., 61 F.3d 123, 129 (2d Cir. 1995)) ("If a plaintiff can show that a defendant's conduct exerted an actual adverse effect on competition, this is a strong indicator of market power. In fact, this arguably is more direct evidence of market power than calculations of elusive market share figures....If a plaintiff can show an actual adverse effect on competition, such as reduced output, we do not require a further showing of market power"); Toys "R" Us, Inc. v. FTC, 221 F.3d 928, 937 (7th Cir. 2000) (no "elaborate market analysis [i]s necessary" where there is "direct evidence of anticompetitive effects"); Re/Max Int'l, Inc. v. Realty One, Inc., 173 F.3d 995, 1018 (6th Cir. 1999) ("an antitrust plaintiff is not required to rely on indirect evidence of a defendant's monopoly power, such as high market share within a defined market, when there is direct evidence that the defendant has actually set prices or excluded competition.").[8]

Consequently, if an antitrust plaintiff can establish with undisputed facts that a defendant successfully raised and maintained prices above competitive levels or

[8] See also Forsyth v. Humana, Inc., 114 F.3d 1467, 1475 (9th Cir. 1997); Rebel Oil Co., 51 F.3d at 1434; Coastal Fuels, Inc. v. Caribbean Petroleum Corp., 79 F.3d 182, 196-97 (1st Cir. 1996); Allen-Myland, Inc. v. IBM Corp., 33 F.3d 194, 209 (3d Cir. 1994); Flegel v. Christian Hosp. Northeast-Northwest, 4 F.3d 682, 688 (8th Cir. 1993); United States v. Baker Hughes, Inc., 908 F.2d 981, 992 (D.C. Cir. 1990); Ball Memorial Hosp. Ins. Inc. v. Mutual Hosp. Ins., 784 F.2d 1325, 1336 (7th Cir. 1986).

excluded competition for a significant period of time, the "monopoly power" element of a Sherman Act Section 2 claim is established as a matter of law. There is no requirement to engage in a market-definition analysis in order to assess relative market shares. When, as here, the evidence conclusively establishes that a defendant charged a supracompetitive price for a product and excluded competition, the defendant cannot refute the conclusion that it had "monopoly power" by advancing arguments concerning the contours of a theoretical market and its relative share in that market.

Therefore, if Kaiser can establish on the undisputed facts that Abbott was able to maintain the price of Hytrin at a level above the price charged for the same drug after the onset of competition, or was able to keep competitors from entering the market, this Court can and should rule on summary judgment that Abbott's monopoly power is established as a matter of law. Making a monopoly power finding in this case does not require the court to find that Abbott acquired or maintained that power unlawfully—that is a separate finding under the second element of a Kaiser's Section 2 claim that will be litigated on additional evidence at trial.

II. THE UNDISPUTED DIRECT EVIDENCE THAT ABBOTT USED ITS PATENT TO MAINTAIN HYTRIN PRICES AT A SUPRACOMPETITIVE LEVEL AND TO PREVENT GENERIC COMPETITION ESTABLISHES THAT ABBOTT POSSESSED MONOPOLY POWER

The undisputed direct evidence in this case establishes that Abbott maintained prices of Hytrin at a supracompetitive level and excluded competition prior to August 1999. (See Statement of Uncontroverted Facts at ¶ 2.) Thus, Abbott possessed monopoly power prior to generic terazosin entering the market in August 1999.

A. Before Generic Terazosin Entered the Market, Abbott Itself Projected that It Would Lose 40% of Its Hytrin Sales within Two Months and 80% of Its Hytrin Sales within a Year

Before generic terazosin came to market, Abbott was the only seller of a pharmaceutical product containing the active ingredient terazosin. (AUF ¶ 52.) Hytrin was extremely lucrative for Abbott, generating $540 million in annual sales and representing more than 20% of its domestic pharmaceutical sales. (See Ex. 3 at 2); see also Kaiser, 552 F.3d at 1038; (AUF ¶ 28.) In those models and memoranda, Abbott predicted that its Hytrin sales would plummet 40% just two months after generic terazosin came to market, and over 80% after a year. (AUF ¶ 29.) Similarly, one of the experts retained by Abbott in the MDL proceedings estimated that Abbott's monthly profits would have dropped $22-25 million per month over the fifteen-month period following Geneva's coming to market in April 1998. (AUF ¶ 53.)

These undisputed facts establish that, prior to generic terazosin entering the market, Abbott, as the sole supplier of terazosin, was clearly aware that it had actual, indeed unfettered, control over the price of Hytrin and knew that it was maintaining the price of Hytrin at a supracompetitive level prior to August 1999. Abbott knew that, once it was no longer the sole supplier of terazosin in the market, its sales volume, revenue, and profits would fall precipitously. (See Statement of Uncontroverted Facts at ¶ 3.) Furthermore, Abbott's understanding that competition would cost it upwards of $22 million per month reflects its understanding that, before August 1999, its price for Hytrin inflated its monopoly profits by that same figure. (See Statement of Uncontroverted Facts at ¶¶ 5,6.)

B. Abbott Paid Geneva $4.5 Million per Month to Stay Out of the Market until August 1999

On April 1, 1998, just two days after Geneva obtained FDA approval of its Capsule ANDA, Abbott reached an agreement with Geneva to prevent generic

terazosin form entering the market. (See Statement of Uncontroverted Facts at ¶ 4.) In exchange for a monthly payment of $4.5 million, Geneva agreed not to market its generic terazosin until the earliest of (1) the sale of generic terazosin by another manufacturer; (2) entry of a final, unappealable judgment concerning the validity of the '207 patent; or (3) February 17, 2000 (the date one of Abbott's other patents expired).[9] (AUF ¶ 20.) By securing the Geneva Agreement, Abbott unquestionably prevented Geneva from marketing generic terazosin so that it could maintain its status as the sole supplier of Hytrin and, thus, continue to charge Kaiser, and others, a supracompetitive price for Hytrin. Indeed, Abbott's willingness to pay Geneva and others millions to stay out of the market shows that Abbott was reaping monopoly profits of some amount greater than the payments contemplated under those agreements—additional direct evidence of Abbott's monopoly power.

The Geneva Agreement is itself sufficient direct evidence of Abbott's monopoly power: "The very fact that the pioneer finds it worthwhile to pay a large exclusion payment tends to establish market power." Herbert Hovenkamp, Mark D. Janis & Mark Lemley, IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law (2004) at 7-37. In fact, in an earlier phase of this case, the MDL Court stated that it was persuaded that Abbott had monopoly power because it was willing and able to make exclusionary payments to generic manufacturers of terazosin to prevent generic terazosin from coming to market. (AUF ¶ 40.)

Thus, the undisputed direct evidence establishes Abbott's ability to maintain its status as the sole supplier of terazosin by excluding others from competing with Hytrin prior to August of 1999. This evidence alone suffices to establish Abbott's monopoly power as a matter of law.

[9] As previously stated, Abbott also reached a similar, multi-million-dollar-per-month agreement with Zenith. (AUF ¶ 23.)

C. Just as Abbott Had Predicted, One Year after Generic Terazosin Entered the Market, Abbott's Hytrin Sales Plummeted Over 75%

Abbott's projections for the effect of generic terazosin on its sales volume and revenue have proved to be remarkably accurate. In July 1999, the month before Geneva entered the market with generic terazosin, Abbott sold nearly 35 million units of Hytrin for a total revenue of approximately $43 million. (AUF ¶ 33.) And by October 1999, two months after Geneva began to sell generic terazosin, Hytrin sales had fallen to just over 20 million units for a total revenue of approximately $25 million—a 42% drop. (AUF ¶ 34.) By August 2000, one year after Geneva began to sell generic terazosin, Hytrin sales had fallen to 11.4 million units for a total revenue of under $10.4 million—a 76% drop. (See Statement of Uncontroverted Facts at ¶ 7; AUF ¶ 35.)

Prior to August 1999, Abbott was the sole supplier of terazosin. (AUF ¶ 27.) With the advent of competition, however, Abbott's sales volume plummeted, including the elimination of its sizeable sales to Kaiser once Kaiser began purchasing generic terazosin from Geneva. (AUF ¶¶ 34, 35.) The undisputed evidence of a precipitous drop in Abbott's Hytrin sales and the resultant 76% drop in revenue once Abbott ceased to be the sole supplier of terazosin establishes that Abbott enjoyed monopoly power until Geneva entered the market in August 1999, creating competition for the first time.

D. Competition Led Abbott to Dramatically Reduce Its Price for Hytrin

Until the Federal Circuit ruled that the '207 patent was invalid and generic terazosin became available, Abbott had sold Hytrin to Kaiser for nearly $0.70 per tablet. (AUF ¶ 2.) Once the Geneva Agreement terminated, Geneva began selling generic terazosin in August 1999, and Abbott offered to sell Hytrin to Kaiser for just $0.10 per tablet—an 86% reduction in price. (AUF ¶ 54.)

There could hardly be more direct and irrefutable evidence that Abbott's pre-generic-entry price was supracompetitive than this instant, dramatic price drop. Before Geneva entered the market in August 1999, Abbott, as the sole supplier of terazosin, charged (and Kaiser paid) $0.70 per tablet. (AUF ¶¶ 1,2.) The instant Geneva entered the market, however, Abbott was willing and able to sell Hytrin to Kaiser for $0.10 a tablet. (AUF ¶ 33) The best evidence of the "competitive price" for Hytrin is the price Abbott offered when generic terazosin came to market and competition existed. It is likewise clear that the $0.70 Abbott charged Kaiser prior to August 1999 far exceeded the "competitive price" and was, therefore, a "supracompetitive" price.

As a matter of law, the above-mentioned, undisputed direct evidence establishes that Abbott enjoyed monopoly power over terazosin until Geneva came to market with generic terazosin in August 1999. This evidence fully supports summary judgment in favor of Kaiser on the issue of Abbott's possession of monopoly power.

CONCLUSION

Kaiser is entitled to summary judgment as to the first element of its Sherman Act Section 2 claim—that Abbott possessed monopoly power—because the undisputed direct evidence shows that Abbott maintained a supracompetitive price for Hytrin and suppressed generic manufacturers of terazosin from entering the market, allowing it to reap excessive monopoly profits.

For these and the foregoing reasons, Kaiser respectfully requests that the Court grant summary judgment in favor of Kaiser and find that Abbott possessed monopoly power in the market before generic terazosin came to market in August 1999.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the 25th day of August 2009, I electronically filed the foregoing Memorandum of Points and Authorities in support of Plaintiff's Motion for Partial Summary Judgment Motion on Monopoly Power with the Clerk of the Court using the CM/ECF system.

By: Linda Sepulvado
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